REMARKS

Claims 1, 15, 16, and 17 were amended to place the claims in condition for allowance. Support for the amendments can be found throughout the specification at, for example, paragraph 11 and Examples 1-4.

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited

Obviousness Rejection

Claims 1-25 were rejected under 35 USC §103(a) as being unpatentable over Lee in view of Friend, US Pat. No. 6,139,865). (Paper No. 12 at 2.)

For the reasons set forth below the rejection, respectfully is traversed.

Lee discloses a chewable tablet a core containing a medicament in a state of jelly or chewable base; and an outer layer of chewable base wrapping the core. (Col. 1, ln. 65 – col. 2, ln. 3.) The medicament in the core was disclosed as being of bitter taste. (Col. 2, lns. 4-5.) Acetaminophen was disclosed as possibly being contained in the core. (Col. 2, lines 9-18.) According to Lee, the jelly base of the core, which contains the above medicament in a state of jelly, may be selected from the group consisting of pectin, sorbitol, maltitol, isomalt, liquid glucose, sugar, citric acid and a flavoring agent. (Col. 2, lns 29-32.) According to Lee, the chewable tablet provides taste mask effect to a bitter tasty medicament, which is contained in the medicament, and better chewing property and taste than the conventional tablets by means of an outer tasty chewable base. (Col. 3, lns. 54-57.)

Friend discloses a taste-masked microcapsule composition for administration of a drug. (Abst.) The drug is coated using a coacervation technique in which the drug is coated with relatively high levels of a polymeric material. (Abst.) The technique involves three phases: the core material phase of the drug to be encapsulated, a coating phase of the drug coating substance and a liquid phase in which the core and the coating materials are dispersed or dissolved. (Col. 1, lns. 54-60.) Data are provided that show average and median scores for microencapsulated ranitidine tablets for taste masking, bitterness, aftertaste and overall acceptance. Figs. 3A-3D and 4A-4D. According to Friend, the particle size of the microcapsules can be in the range of a few microns to a thousand microns or more. (Col. 8, lines 31-36.)

In making the rejection, the Examiner asserted that "Lee teaches a chewable pharmaceutical dosage form comprising a core containing an active ingredient and an outer layer." (Paper No. 20031222 at 2.) The Examiner contended that "the dosage form demonstrates improved organoleptic properties when chewed, such as taste. (*Id.*) The Examiner

asserted that the "core may be in the form of a jelly, with the base of the jelly selected from a group that includes pectin. The Examiner further asserted that gelatin may be used in either the core or outer layer to maintain hardness and extension property in the dosage form. The Examiner stated that the "outer layer may take a variety of forms, including hard candy and that acetaminophen is listed as a possible active ingredient in core. The Examiner concluded that Lee contains and enabling disclosure of a dosage form with a unitary core.

The Examiner contended that Friend "teaches taste-masked microcapsule compositions for the administration of a drug," including acetaminophen and ibuprofen. (Paper No. 20031222 at 3.) The Examiner further contended that Friend discloses that "[t]he compositions may be incorporated into a variety of dosage forms, including chewable tablets, in amounts ranging from 10% to 95% by weight of the dosage form." The Examiner further asserted that Friend discloses that "preferred [] microcapsules range in size from approximately 30 microns to 800 microns."

The Examiner asserted that both Lee and Friend "deal with the administration of drugs in pharmaceutical compositions with improved organoleptic properties." The Examiner reasoned that "one of ordinary skill would be motivated to incorporate the composition disclosed in Friend into the dosage form of Lee in order to provide a pharmaceutical dosage form wherein the active ingredient is further taste-masked without an undue delay on the release of the drug." The Examiner then concluded that "it would have been obvious to one of ordinary skill in the art to combine the teachings of Lee and Friend into the objects of the instant application. (Paper No. 20031222 at 3.)

The Examiner then opined that "[a]s Friend states that the disclosed compositions may be incorporated in chewable tablets, it is the position of the Examiner that one of ordinary skill in the art could combine the disclosures of the prior art with a reasonable expectation of success."

The determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. For a *prima facie* case of obviousness to be established, it is well settled that the teachings from the prior art itself must appear to have suggested the claimed subject matter to one of ordinary skill in the art at the time the invention was made. The mere fact that the prior art could be modified as proposed by the Examiner is not sufficient to establish a *prima facie* case of obviousness.

In setting forth the analysis for the instant rejection, the Examiner appears to have fallen into the trap of hindsight reconstruction. This is because the record memorializing the

Examiner's analysis of the grounds of rejection is based solely on current knowledge. The record does not indicate that the Examiner undertook any analysis that was placed at the time the invention was made. Such a time limitation in conducting an obviousness inquiry is a necessary protection to prevent the Examiner from falling into the powerful attraction of conducting hindsight-based obviousness analysis. Nonetheless, the Examiner has succumbed to this attraction and used hindsight reconstruction to make out the rejection. For this reason alone, the rejection is improper and should be withdrawn.

The claims have been amended to place them in condition for allowance.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP § 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

Respectfully submitted,

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Dated: April 8, 2004
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